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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,014	12/04/2001	Chen Xing Su	10209.276	6898

21999 7590 10/11/2006

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EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1618

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,014

Applicant(s)

SU ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 September 2006.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-10,12 and 13 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-10,12 and 13 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, all received on 06 September 2006.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is rendered moot with the cancellation of that claim.

The rejection of Claims 1, 3-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 9, 10, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over Gidlund is maintained.

Response to Arguments

The applicant's arguments, received on 06 September 2006, have been considered, but are not found to be persuasive.

The examiner considers the property of selective cyclooxygenase-2 inhibition to be implicit and inherent to the disclosure of the prior art. As the art has already shown guidance that the invention of the Gidlund reference is useful for treating various conditions of pain, such as menstrual cramps, arthritis, sprains, and injuries, the examiner considers such a disclosure to be further guidance and evidence towards that rationale. The applicant is reminded that a composition known in the prior art does not become patentable upon the discovery of a new property. See MPEP § 2112. The burden remains on the applicant to show the unobvious difference between the instantly claimed invention and the prior art that would render patentability unto the instantly claimed invention.

Furthermore, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). By the unit conversions as seen below between dosages as expressed in mL per kg of body weight, as disclosed by the prior art, and in fluid ounces as recited in Claims 9 and 12, it is the position of the examiner that the instant claimed methods are not patentably distinct above the prior art.

The applicant's arguments do not overcome the rejection under 35 U.S.C. 112, because it is entirely unclear how the portion of the instant specification cited by the applicant supports the recitation in the instant claims of administering processed *Morinda citrifolia* juice with each dose being less than 0.1 mL per kg of body weight of the patient. How such a claim limitation can be

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properly supported by and derived from the instant specification has not been made clear at any point in the prosecution of this case. As such, the rejection under 35 U.S.C. 112 will be maintained.

As stated in a previous Office Action, the applicant has attempted to distinguish the instant claims over the disclosure of the prior art by stating that the a patient having a mass of 70 kg would be administered 7 mL of liquid extract per day. However, a very simple unit conversion would show that 7 mL is equivalent to less than 0.25 fluid ounces. The applicant has simply decided to ignore this important calculation, since other claims, such as Claims 9 and 12, require the administration of 2 to 3 fluid ounces. This would mean that at the ratio of less than 0.1 mL per kg of body weight of a patient, that patient would have to have a body mass of at least 590 kg, well over half of a metric ton.

It is clear then that the claim limitation of a daily dosage of less than 0.1 mL per kg of body weight of a patient, as introduced into the claims in the amendment of 25 November 2005, is merely nothing more than an attempt to maneuver around what has been taught by the prior art. This is evidenced by the fact that in the specification as originally filed, there is never any explicit mention of dosages expressed in the units of mL per kg of body weight of the patient. However, the expression of dosages in such units is readily apparent in the Gidlund reference. In that reference, the lower end of the range of dosages is 0.1 mL per kg of body weight of the patient, as cited by the applicant in the seventh line on page 8 of the present response. There appears to be a strong indication that the recitation in Claim 1 of a dosage of less than 0.1 mL per kg of body weight of the patient was taken directly from the disclosure of the prior art, rather than from the what was properly enabled by the instant specification, and incorporated into the

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instant claims in a clumsy attempt to amend the claims around the explicit disclosure of the prior art. This examiner refuses to grant patentability to the instant claims where a claim is amended by the conditions as described above. For these reasons, the instantly claimed invention remains rejected.

Correspondence

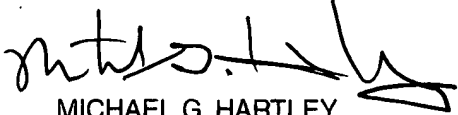
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
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sj0


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER